Texas State Board of Pharmacy Laws and Rules Update Webinar FAQs and Troubleshooting Tips

- We will be using the *Chat* box to deliver general information.
 If you have questions, please use the *Q&A* box to submit.
- You may send all follow-up questions or handout requests to
- · You do not need a microphone just log in to watch and listen.
- · We will be doing periodic sound checks before the presentation begins.

 - Call 1-415-55-50003
 Enter access code/event number for this webinar (found in the Event Info tab and will be posted in the "Chat" box pane)

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- Receiving Credit

 - Lock for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 <u>business</u> days from now
 An email notification will be sent to you when these are available.
 Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account.
 - ning Account

 Please note: This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. However, it is NOT ACPE certified and will not appear in your CPE

 Monitor account.



TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S. **Director of Professional Services** July 7, 2016



Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Pharmacies:
- Review pharmacy related legislation passed by the 2015 Legislature; and
- Review some current issues facing the Board.



Board of Pharmacy Members

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Recently Adopted Rules



Grounds for Discipline

- Effective Date: December 6, 2015.
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual <u>exhibits abusive</u>, <u>intimidating</u>, <u>or threatening behavior toward a board member or employee</u> during the performance of a member's or employee's lawful duties.



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Grounds for Discipline

- Effective Date: March 10, 2016.
- It is a ground for discipline of a pharmacy license if the owner, managing officer(s), or other pharmacy employee(s) <u>exhibits</u> <u>abusive</u>, intimidating, or threatening <u>behavior toward a board member or</u> <u>employee</u> during the performance of a member's or employee's lawful duties.



TEXAS STATE BOARD OF PHARMACY

Pharmacist-in-Charge

- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
 - Class B Pharmacy; or
 - Class C Pharmacy in a hospital with 101 beds or more.



Administration of Immunizations and Vaccines

- Effective Date: December 6, 2015.
- Before preparing an immunization/vaccine and between each patient contact:
 - Pharmacist must:
 - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
 - wash their hands with soap and water.
 - If gloves are worn, pharmacists must change gloves between patients.



TEXAS STATE BOARD OF PHARMACY

Rules Adopted by the Board at the May 3, 2016 Meeting

- Will become effective in late May or early June 2016.
- The transfer of prescriptions must be completed within <u>four business hours</u> of the request.



TEXAS STATE BOARD OF PHARMACY

Pharmacists and Pharmacy Technicians



Pharmacist's Continuing Education

- Effective Date: March 17, 2013.
- Pharmacists can receive credit for programs approved by AMA as Category 1 CME.
- Pharmacists must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



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Pharmacy Technician's Continuing Education

- Pharmacy Technicians must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



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Pharmacy Technician's Continuing Education (cont.)

- Effective Date: <u>September 14, 2015</u>.
 Amendments to §297.8 (Continuing Education) rules to:
 - Decrease the number of in-service hours from 10 to 5 hours;
 - Clarify the requirements for CE; and
 - Clarify the types of programs that count for continuing education.



Licensing Fee Changes

License	Renewal Fee Effective October 1, 2015	Change
Pharmacist	\$276	\$25 decrease
Pharmacies	\$452	\$80 decrease
Pharmacy Technicians	\$77	\$19 decrease
Pharmacy Technician Trainees	\$52	\$10 decrease

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Conditions Receiving "Warning Notices" FY2015



Number of Inspections

Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%

Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%

Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*
Records	731
Sterile Preparations	647
Pharmacy Technicians	564
Drug/Stock Environment	421
Prescriptions	335
Inventory	319
* One pharmacy may receive multiple Warning Notice violations.	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Records		731
Records Not Available	314	
Absence of R.Ph. Record	66	
Rx Not Separated	17	
Rx Records Not Numerical Order	25	
Improper Transfer of RX copies	3	
Invoices Not Separated/Retrievable	122	
Records for Non-Sterile Compounds	169	
No Written Information on RX	10	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Sterile Preparations		647
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytoxic/Bio Procedures	2	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		564
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		421
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Prescriptions		335
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Inventory		319
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	

Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.

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Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



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Violations NOT Resulting in Warning Notices

- Egregious Conditions
 - Dispensing CIIs pursuant to prescriptions not issued on an Official Form;
 - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
 - Pharmacy closed and did not notify TSBP of closing;
 - Operating without a PIC for an extended period of time (i.e., 3 months or more).



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Violations NOT Resulting in Warning Notices

- Continuing threat For example:
 - Impaired pharmacist on duty; or
 - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to "cease and desist" sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing



Pharmacy Related Legislation Passed by the 2015 Legislature



S.B. 195 by Sen. Schwertner

- This bill:
- Moves the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminates the Texas Controlled Substance Registration program.



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Timeline for Transfer of the PMP Program

- November 2015 RFP for the new PMP issued by TSBP.
- January 2016 <u>Appriss selected as the vendor.</u>
- February May 2016 System installation at TSBP.
- May/June 2016 –Testing of program.
- **September 1, 2016** − NEW PMP goes live



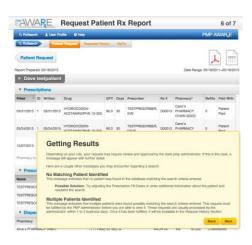


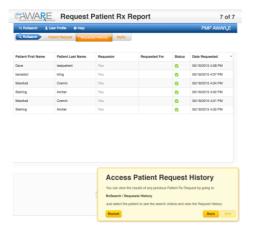












H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
 - Rules adopted by the Board in February 2016.
 - §295.16 Administration of Epinephrine by a Pharmacist.
- This bill amends the Pharmacy Act to:
 - Allow a pharmacists to administer epinephrine, using an auto-injector, to a patient in an emergency situation.



H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
 - Specify a pharmacist:
 - May not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.
 - Who administers epinephrine through an autoinjector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.



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Bullard pharmacist saves patient's life thanks to new law

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Bullard pharmacist Eily Baker saved a woman's life, thanks to a new law enacted in Texas earlier this year A customer walked in the Brookshire's pharmacy in

If was preffy clear that she needed more than Benadryl, because her eyes were swollen shut, and the had trouble headbloo." Mr. Steer and

The Bullard native grabbed an EpiPen and nijected the medicine into the patient's thigh. Ms. Bakers sall be patient let bethe soon after and could breshi again. She monitored the woman for a white until the seeking had gone down, and she could breather freely; as prepared. She then called \$111, notfles her physician and documented what happened.

Before, she would not have been able to legally administer the drug to a patient. In January, Texas legislation passed a law that allows a pharmacest to administer an epinephrine auto-injector to a patient an emergency shatation. It also provides tability protections for administerant the drug.

Current Issues



Sunset Review

- Texas Pharmacy Act, Sec. 551.005.
 Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). <u>Unless continued in existence as</u> <u>provided by that chapter, the board is</u> <u>abolished and this subtitle expires September</u> 1, 2017.



Sunset Review Time Line

- August 2015.
 - TSBP prepares a Self-Evaluation Report.
- October 2015 March 2016.
 - Sunset staff reviews the agency.
- Late March 2016.
 - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response



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Sunset Review Time Line (cont.)

- April 2016.
 - Sunset staff report published.
- June 23-24, 2016.
 - Sunset Commission holds a public hearing to receive public comment on the agency.
- Summer 2016.
 - Commission decisions are issued.
- January May 2017.
 - 2017 Legislative Session



TEXAS STATE BOARD OF PHARMACY

TSBP Website www.pharmacy.texas.gov













Final Reminders

- Receiving Credit
 - Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 days from now
 - An email notification will be sent to you when these are available
 - You will have 30 days from the date they are posted to complete them.
 - Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account.

Trouble accessing your Lifelong Learning Account? Questions about your attendance?

Call the help desk:

1-800-215-0641 Select Option 1



Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.

For questions about today's presentation, please email us at:

education coordinator @pharmacy.texas.gov

